

SERVICES

# MEDICAL AFFAIRS

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Committed to fulfill your pursuit of bringing hope and smile to the patients

**At COD, our medical affairs team is quintessentially responsible for the development, writing, review and interpretation of standalone or end-to-end clinical documents for scientific accuracy and medical expert review to meet the regulatory compliance for proof concept studies, drug phase trials, medical device trials, drug-device combination trials, post-marketing commitment trials, academic clinical trials and patient based generic molecule studies.**

## Clinical Concept Development

- Extensive literature search
- Key enrollment criteria
- Type of studies and its design
- Objectives and endpoints
- Liasoning with KOLs

## Medical Monitoring

- Medical inputs in clinical documents prepared by medical writers
- Medical inputs for sample size estimation
- Preparation and/or review of Medical Monitoring Plan (MMP)
- Preparation and/or review of Safety Management Plan (SMP)
- Eligibility review
- 24 x 7 availability for discussion & response to medical emergencies
- Review of serious adverse event/pregnancy cases
- Protocol deviation review and discussion
- Medical/Safety line listing review and discussion
- Medical coding review
- AEFI review in a clinical trial
- Review of emergency unblinding request
- Development and delivery of CIOMS
- Analysis of similar events and its review

## Medical Writing

- Investigator's Brochures (IB)
- Clinical study protocols / clinical investigation plan
- Consent documents, patient scales, patient diary cards, etc.
- Comprehensive (ICH-E3 compliant) / Abbreviated / Synoptic clinical study reports
- Clinical Investigation Reports
- Clinical and non-clinical summaries and overviews of the common technical document (CTD)
- Briefing documents for various regulatory agencies

# MEDICAL AFFAIRS

## Why COD – Medical Affairs:

**+10**

Vaccine/drug  
development experience

**+150**

Clinical Study Protocols  
and associated pre-study  
documents (overall team  
experience)

**+20**

global clinical trial's  
medical monitoring  
experience as  
stand-alone projects to +5

**+56000**

Patients Medical  
Monitoring ongoing for  
02 COVID-19 Global  
Clinical Trials

**+80**

Clinical Study Reports  
– ICH-E3 compliant  
(overall team experience)

**+37**

Years of cumulative  
Medical/Clinical  
experienced Medical  
Monitors

## KOL Council

Industry veteran Medical  
experts across  
Therapeutic Areas

## Qualified experts:

**Medical Monitors**  
(M.D. – Pharmacology)  
**Medical Writers**  
(M.Pharm – Pharmacology)

Dynamic and  
professional medical  
monitors & medical  
writers with regulatory  
compliant orientation